Australian Government
Department of Industry, Science, Energy and Resources

Approach to Market

Proposals to establish an end-to-end onshore mRNA manufacturing

Questions and Answers from potential respondents

21 May 2021

1. Question: 2021 Budget Measure

How do negotiations with existing manufacturers outlined in the 2021 Budget Measure 'COVID-19 Vaccine Manufacturing Capabilities' relate to this approach to market?

Answer:

You can find the 'COVID-19 Vaccine Manufacturing Capabilities' budget measure in the Budget 2021-22 Paper number 2, located on page 134.

This approach to market is complementary to any current discussions the Australian Government is engaging in directly with relevant mRNA vaccine IP owners to establish mRNA manufacturing facilities in Australia. The Australian Government will consider proposals from this approach to market alongside the outcomes of the discussions with mRNA vaccine IP owners. This will help to secure the best mRNA capability for Australians.

There is no guarantee that this process will result in the Australian Government undertaking any grant, procurement activity or other financial support for any proposal that involves any respondent to this approach to market.

The Australian Government may not undertake any open procurement or grant process following this approach to market and may seek to enter into arrangements directly with one or more respondents to this approach to market or with any other entity (including any existing mRNA vaccine IP holder).

The Australian Government will be closely considering the proposals it receives through this process. This approach to market is the opportunity for providers to demonstrate their future capability and explain what government involvement, assistance or support could make that capability a reality.

2. Question: Australian manufacturers

Is this approach to market restricted to Australian manufacturers?

Answer:

No. However, we know that Australian manufacturers could, in principle, establish and operate a competitive mRNA manufacturing capability, and there is clear interest to do so.

This approach to market is an opportunity for local manufacturers to provide solutions. We know you can do it, now we need detailed proposals.

3. Question: Joint proposals

Will you consider joint proposals?

Answer:

Yes. We would consider a modular or multi-partner approach in delivering the end-to-end capability. Partnerships, consortia, leveraged funding options and so on will all be considered.

A consortium should submit a single proposal to this approach to market on the basis that one legal entity will take full responsibility as it is the Australian Government's intention that it enters into an arrangement with a single legal entity to establish the capability. The proposal should provide full details of that legal entity, the consortium members and any proposed subcontractors.

Individual entities/companies may be part of multiple proposals/consortia.

4. Question: Modern Manufacturing Initiative

Can I submit a proposal through this approach to market and also receive funds from the Modern Manufacturing Initiative?

Answer:

The Medical Products Road Map identifies mRNA vaccines as a growth opportunity. The road map is guiding investments under the Modern Manufacturing Initiative – the centrepiece of Australia's Modern Manufacturing Strategy.

You can submit a proposal through the approach to market and also seek or receive funds under the Modern Manufacturing Initiative. However, the government does not intend to fund the same project activities under both the Modern Manufacturing Initiative and any support arrangements following this approach to market.

5. Question: Business case

Can you release the business case for onshore mRNA manufacturing in Australia?

Answer:

The business case is contributing to government deliberations and will not be released publicly.

6. Question: States and territories

How does this approach to market interact with state and territory mRNA manufacturing announcements?

Answer:

Proposals may involve state and territory governments. If a state or territory government is going to provide support to a proposal, details of that support should be included in the

proposal but it is not a requirement that the state or territory be a member of a consortium or a subcontractor.

It is expected that respondents may engage with state and territory governments to develop their proposals to provide maximum value to Australia. If respondents anticipate a role for state or territory governments in their proposal for onshore mRNA manufacturing capability, the Australian Government's preference is for this engagement to occur prior to proposal lodgement (and for any state/territory government support to be reflected in the proposal).

7. Question: Money

How much money has been put aside for this?

Answer:

Given the inherent commercial nature of this process we are not publishing funding information associated with establishing an onshore mRNA manufacturing capability.

We are asking for proposal submissions that are fully costed to enable the Australian Government to make an informed decision about how to secure the best mRNA capability for Australians.

8. Question: mRNA vaccines

What are mRNA vaccines?

Answer:

The Department of Health has resources on vaccines and Australia's vaccine rollout, including information about how mRNA vaccines work.

As a new technology, the true potential of mRNA vaccines remains uncertain, and information about it is always evolving. However, mRNA technology has proven it can support effective and rapid COVID-19 vaccine development and manufacturing. It seems likely that a range of other applications will follow.

Read our introductory information on mRNA vaccines, including its manufacturing and why it has a promising future.

How mRNA differs from traditional vaccines

Producing traditional vaccines is relatively time consuming. For example, it requires the replication of a viral pathogen (for example, the influenza virus) or the viral vector in mammalian cells or chicken eggs. It may require production of protein subunits by biological processes (for example, using bacteria as a biological factory). These vaccines are then injected into the body generating an immune response.

mRNA vaccines, however, are produced by chemical reactions, rather than biological processes like those described above. The mRNA vaccine delivers the genetic code directly into the body, without the aid of a viral vector, to trigger an immune response.

How mRNA vaccines can help speed up development time

As demonstrated in the COVID-19 pandemic, the promise of mRNA vaccines is the potential for faster development and production than traditional vaccines, while maintaining strong efficacy. In particular:

- **Shorter development time**. The time from pathogen (virus) identification to vaccine production is lower for mRNA vaccines. Developing a new candidate takes approximately 3 weeks with mRNA versus 2 to 3 months with cell-based technologies (which require a lengthy process of virus selection, incubation, and fluid purification). For seasonal influenza, it takes about 6 months from identification of circulating influenza strains to produce traditional vaccines. For mRNA, once the genetic code is identified, vaccines can proceed straight to testing.
- **Shorter production time**. Traditional vaccines are grown using complex biological processes, like egg or mammalian cell-based cultivation (where viruses are grown in living cells). On the other hand, the RNA that forms the basis of mRNA vaccines can be synthesised from chemical reactions rather than biological processes. Removing the need to obtain/grow cells, and growing/producing the antigen within them, significantly shortens production times and complexity. The production process is also repeatable and scalable, once a process is established, it can be reused for multiple vaccine candidates.

mRNA applications beyond COVID-19

Scientists have suggested mRNA as a promising technology for the delivery of vaccines and pharmaceuticals for decades. The first successful animal trials involving transcribed mRNA were published in 1990. However, there were delays in developing effective mRNA therapeutics due to challenges like mRNA instability, and inefficient in vivo delivery/organ targeting.

In recent years significant advances have been made in the development of mRNA vaccine technology, such as technologies like lipid nanoparticles to deliver mRNA into cells.

Some of the most promising mRNA applications beyond COVID-19 are vaccinations for other infectious diseases. The recent success in COVID-19 mRNA vaccines opens up the possibility of new disease vaccines including influenza, Zika, HIV-1, and dengue fever.

mRNA cancer vaccines represent another exciting potential opportunity. Additionally, therapeutics for managing and treating other diseases are in early-stage development. This includes candidates for the treatment of diseases like myocardial ischaemia, autoimmune disorders, and rare metabolic diseases.